WO 2004/063712 PCT/US2004/000447

CLAIMS

What is claimed is:

1. A method of diagnosing cancer in a patient, comprising:

- a) obtaining a test sample from a patient;
- b) measuring the level of thymosin β 16 in the test sample; and
- c) comparing the level of thymosin $\beta 16$ in the test sample with the level of thymosin $\beta 16$ present in a normal control sample;

wherein a higher level of thymosin $\beta 16$ in the test sample as compared to the level in the normal control sample is indicative of cancer.

- 2. The method of claim 1, wherein said test sample and said normal control sample are selected from the group consisting of blood, tissue, serum, stool, urine, sputum, cerebrospinal fluid, nipple aspirates, and supernatant from cell lysate.
- 3. The method of claim 1, wherein the cancer is prostate cancer, lung carcinoma, breast carcinoma, thyroid carcinoma, brain cancers (cerebellum, medulloblastoma, astrocytoma, ependymoma, glioblastoma), pancreatic carcinoma, ovarian carcinoma, eye cancer (retinoblastoma), muscle (rhabdosarcoma), lymphoma, stomach cancer, liver cancer, colon cancer, kidney cancer.
- 4. A method for prognostic evaluation of a patient suspected of having or having cancer comprising:
 - a) measuring the level of thymosin β16 in a test sample obtained from a patient;
 - b) comparing the level determined in step (a) to a range of thymosin β16
 known to be present in a biological sample obtained from a normal
 patient that does not have cancer; and
 - c) evaluating the prognosis of said patient based on the comparison of step (b), wherein a high level of thymosin β16 in step (a) indicates an aggressive form of cancer and therefore a poor prognosis.

WO 2004/063712 PCT/US2004/000447

5. The method of claim 4, wherein said test sample is selected from the group consisting of blood, tissue, serum, stool, urine, sputum, cerebrospinal fluid, nipple aspirates, and supernatant from cell lysate.

- 6. The method of claim 4, wherein the cancer is prostate cancer, lung carcinoma, breast carcinoma, thyroid carcinoma, brain cancers (cerebellum, medulloblastoma, astrocytoma, ependymoma, glioblastoma), pancreatic carcinoma, ovarian carcinoma, eye cancer (retinoblastoma), muscle (rhabdosarcoma), lymphoma, stomach cancer, liver cancer, colon cancer, kidney cancer.
- 7. The method of claim 1 or 4, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 mRNA.
- 8. The method of claim 7, wherein the mRNA is detected by use of an RNA dependent polymerase chain reaction.
- 9. The method of claim 7, wherein the mRNA is detected by Northern blot analysis by hybridizing mRNA from said test sample or said control sample to a thymosin β16 nucleotide probe.
- 10. The method of claim 7, wherein the mRNA is detected by DNA microarray analysis.
- 11. The method of claim 1 or 4, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 protein.
- The method of claim11, wherein thymosin β16 protein level is measured by Mass Spectrometry.
- 13. The method of claim 11, wherein the method of measuring the level of thymosin β16 levels comprises the steps of:
 - a) contacting a sample or preparation thereof with an antibody or antibody fragment which selectively binds thymosin β16; and
 - b) detecting whether said antibody or said antibody fragment is bound by said sample and thereby measuring the levels of thymosin $\beta 16$ present.
- 14. The method according to claim 13 wherein said antibody, or said antibody fragment, is detectably labeled.

WO 2004/063712 PCT/US2004/000447

15. A kit for measuring thymosin β16 levels comprising separate vials containing antibodies, or antibody fragments, which selectively bind human thymosin β16.

16. A kit for measuring thymosin β16 levels comprising at least one polynucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO:2 or SEQ ID NO:3.